UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/055,744	04/07/1998	CHARLES D. Y. SIA	1038-746-MIS	4350

7590 01/09/2008

MICHAEL I STEWART
SIM AND MCBURNEY
330 UNIVERSITY AVENUE 6TH FLOOR
TORONTO, M5G1R7
CANADA

EXAMINER	
LE, EMILY M	
ART UNIT	**PAPER NUMBER**
1648	

MAIL DATE	DELIVERY MODE
01/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/055,744	SIA ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. In view of the Appeal brief filed on October 09, 2007, PROSECUTION IS HEREBY REOPENED. New ground(s) of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Bruce Campell/
Supervisory Patent Examiner
Art Unit 1648

Status of Claims

2. Claims 2-3 are cancelled. Claims 1 and 4-11 are pending and under examination.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1 and 5-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Vitiello et al.[1]

The claims are directed to the method of generating an HIV specific cytotoxic T cell response in a host possessing MHC class I HLA A2 molecules comprising administering to the host a T helper molecule, and the subsequent administration of a mixture of T helper molecule and a T cell inducing HIV molecule. Claim 5, which depends on claim 1, requires the T helper molecule to be administered with an adjuvant. Claim 6, which depends on claim 1, requires the T cell inducing molecule to comprise a peptide having an amino acid sequence that is a portion of an HIV antigen, wherein said peptide comprises at least one T cell epitope.

Vitiello et al. teaches a method comprising the administration and re-administration of a T-helper molecule, T-cell inducing HIV molecule and an adjuvant to a human host, which possesses MHC class I HLA A2 molecules. [Claims 11 and 16-17,

in particular.] The T cell inducing HIV molecule that Vitiello et al. teaches comprise a peptide having an amino acid sequence that is a portion of an HIV antigen, wherein said peptide comprises at least one T cell epitope. [Columns 41-42, in particular.]

While it is noted that the method of Vitiello et al. does not specifically state that the administration of the molecules results in the generation of an HIV specific cytotoxic T cell response, the method of Vitiello et al. does include the administration of T cell inducing molecules. The administration of T cell inducing molecules would necessarily lead to the generation of HIV specific cytotoxic T cell response. Therefore, while not specifically noted by Vitiello et al., the method of Vitiello et al. inherently would generate an HIV specific cytotoxic T cell response.

Additionally, it is noted that the claimed invention does not require the administration of the T cell inducing HIV molecule with the T helper molecule during the initial administration, however, it should be noted that the claims recite the transitional term "comprises". This transitional term provides for the administration of a T cell inducing HIV molecule with the T helper molecule during the initial administration.

In summation, Vitiello et al. teaches a method that is the same as the claimed invention. Therefore, Vitiello et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

---

[1] Vitiello et al. U.S. Patent No. 6419931, filed February 16, 1994.

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 4, 6 and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vitiello et al., as applied to claims 1 and 6.

Claim 4, which depends on claim 1, limits the T helper molecule to SEQ ID NO: 10. Claim 8, which depends on claim 6, requires the T cell inducing HIV molecule be a lipopeptide. Claim 9, which depends on claim 8, requires the lipid to be palmitoyl or cholesterol.

The significance of Vitiello et al., as applied to claims 1 and 6, is provided above.

Vitiello et al. did not disclose the administration of a T helper molecule that has the same amino acid sequence as claimed SEQ ID NO: 10 with a T cell inducing HIV molecule. However, Vitiello et al. does teach a T helper molecule that has the same amino acid sequence as claimed SEQ ID NO: 10, and suggest the administration of T helper molecule with T cell inducing molecules. [Lines 1-25, column 25 and claim 11, in particular.] Hence, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to administer the T helper molecule having the same amino acid sequence as claimed SEQ ID NO: 10 with a T cell inducing HIV molecule. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so stimulate an HIV specific immune response in a host. One of ordinary skill in the art, at the time the invention was made would have had a reasonable expectation of success for doing so because Vitiello et al. teaches the

stimulation of an HIV specific immune response with the administration of T helper molecule and T cell inducing HIV molecule.

Additionally, the T cell inducing HIV molecule administered in the method of Vitiello et al. is not lipopeptide. However, Vitiello et al. does suggest the use of a lipopeptide version of the T cell inducing molecule. Vitiello et al. specifically teaches that the lipidation of at least the T cell inducing molecule or the T helper molecule is necessary for the induction of a cytotoxic T cell (CTL) immune response when the molecules are formulated in saline. [Lines 1-3, column 37, in particular.] The lipids that Vitiello et al. teaches include palmitoyl. Hence, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to lipidate the T cell inducing HIV molecule in the method of Vitiello et al. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to facilitate the induction of a cytotoxic immune response when the molecules are formulated in saline. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because Vitiello et al. teaches the lipidation of the peptides to induce CTL response.

7. Claims 1 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vitiello et al., as applied to claims 1 and 6., in view of van Baaleen et al.[2]

Claim 7, which depends on claim 6, requires that the T cell inducing HIV molecule is a portion of the Rev protein.

The significance of Vitiello et al., as applied to claims 1 and 6, is provided above.

---

[2] van Baalen et al. U.S. Patent No. 6024965, filed 10/18/1996.

While Vitiello et al. discloses many T cell inducing HIV molecules, it is not readily apparent if these molecules are directed to a portion of the Rev protein. However, Vitiello et al. does suggest the use of other T cell inducing HIV molecules. [Columns 41-42, in particular.]

At the time the invention was made, T cell inducing HIV molecules that are a portion of the Rev protein were well known in the art. van Baaleen et al. discloses several T cell inducing HIV molecules having a portion of the Rev protein. The T cell inducing HIV molecules of van Baaleen et al. have the same amino acid sequence as SEQ ID NOS: 3 and 8, as set forth in Table II of Applicant's disclosure. Thus, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to use other T cell inducing HIV molecules, including those disclosed by van Baaleen et al. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to stimulate an HIV specific immune response in a host. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the use of alternatives, especially when they are functional alternatives, is routine practiced in the art.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1 and 4-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 7105164. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claim 11 is directed at a method of generating an HIV-specific cytotoxic T-cell (CTL) response in a host possessing MHC class I HLA A2 molecules, which comprises:

administering to the host a T-helper molecule to prime T-helper cells of the immune system of the host, said T-helper molecule being CLP-243 (SEQ ID NO:10) and subsequently administering to the host a mixture of said T-helper molecule and a T-cell inducing HIV-derived molecule to generate an HIV-specific T-cell response in the host, said T-cell inducing HIV-derived molecule being a lipopeptide which is CLP-175 or CLP-176.

Claim 3 of the U.S. Patent is directed to A method of generating an HIV-specific cytotoxic T-cell (CTL) response in a host, which comprises: administering to the host a T-helper molecule to prime T-helper cells of the immune system of the host, said T-helper molecule being CLP-243 (SEQ ID NO:10) and subsequently administering to the host a mixture of said T-helper molecule and a T-cell inducing HIV-derived molecule to generate an HIV-specific T-cell response in the host, said T-cell inducing HIV-derived molecule being a lipopeptide which is CLP-175 or CLP-176 and an adjuvant.

The difference between the claimed invention and the invention of the issued patent is: The issued patent does not require the host to possess MHC class I HLA A2 molecules. However, it is noted that the specification of the issued patent also discloses that the molecules used in the method of the issued patent is capable of inducing a CTL response in hosts possessing MHC class I HLA A2 molecules. Thus, while the claims of the issued patent do not specifically specify that the host possess MHC class I HLA A2 molecules, the claims of the issue patent are inherently directed to such.

The above rejection is, in part, based on the specification of a previously issued patent, rather than the claims. In support of the use of this material, the examiner notes the following excerpt from MPEP section 804 II(B)(1):

> When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.
>
> The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

Thus, the courts have held that it is permissible to use the specification in determining what is included in, and obvious from, the invention defined by the claim on which the rejection is based. This is true even where elements are drawn from the specification describing the claimed invention which are not elements in the claim itself.

Conclusion

10. No claims are allowed. SEQ ID NO: 10 is free of the prior art.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily M. Le/
Patent Examiner
Art Unit 1648

/E.Le/